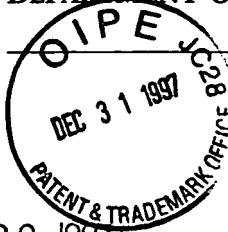




DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service



Food and Drug Administration
Rockville MD 20857

DEC 29 1997

#29

Re: Astelin®
Docket No. 97E-0014

Stephen G. Kunin
Deputy Assistant Commissioner for
Patent Policy and Projects
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, D.C. 20231

Dear Mr. Kunin:

This is in regard to the patent term extension application for U.S. Patent No. 5,164,194 filed by Astra Medica AG under 35 U.S.C. § 156. The patent claims the human drug product Astelin® (azelastine hydrochloride), New Drug Application (NDA) 20-114.

In the April 4, 1997 issue of the Federal Register (62 Fed. Reg. 16167), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before October 1, 1997, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely,

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Kevin B. Clarke, Esq.
Carter-Wallace, Inc.
1345 Avenue of the Americas
New York, NY 10105